

**TEMPLATE FOR PEER REVIEW COMMENTS
STUDY RELATED TO ARTICLE 10 OF THE NAGOYA PROTOCOL**

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Title of document reviewed:	Study to Identify Specific Cases of Genetic Resources and Traditional Knowledge Associated with Genetic Resources that Occur in Transboundary Situations or for Which it is not Possible to Grant or Obtain Prior Informed Consent	
Comments on the study on traceability and databases		

0	0	<p>General comments</p> <p>This study will be of high relevance for further political discussions not only related to Article 10 NP, but also to a potential introduction of a multilateral benefit sharing mechanism, the potential regulation of Digital Sequence Information (DSI) and the access and usage of biological material stored in and accessed from collections.</p> <p>Thus, the study deserves a sound scientific base and has to meet high quality criteria. Therefore we would welcome recognition of the following suggestions to improve the study.</p> <ul style="list-style-type: none"> • Quantitative aspects The study mandate was to identify “specific cases”, but it does not address the question “What percentage of total genetic resources might fall into these categories?” Answering this question, even partially or superficially, would have far-reaching implications on any potential global multilateral benefit sharing mechanisms (GMBSM) that might be considered by the Parties. We suggest a high-level review of the relevant scientific literature, if necessary, with support from scientific stakeholders to compile a more holistic view. The case study approach runs the risk of implying that these examples are “exceptions to the rule” rather than potentially actually representing large amounts of GR or, in some domains of life, practically all GR in a given taxonomic group. • Invasive species Invasive or exotic species are not considered in the study. Considering that invasive species may have a huge negative impact on ecological equilibria, habitats and biota as well as crops, we would like to stress, that those countries which claim sovereign rights over genetic resources including invasive species could face legal risks (e. g. indemnity claims). • Scope of study The authors apply GMBSM to existing examples. According to their mandate, the authors do not cover non-monetary benefit sharing. However, the focus on GMBSM is too narrow, as it ignores the contribution of non-monetary benefit sharing mechanisms. These Mechanisms deliver important contributions to the implementation of the CBD as well as to the Aichi Targets, Post 2020-process and the Sustainable Development Goals (especially in “transboundary” situations). We kindly request the CBD secretariat to also consider and examine non monetary benefit sharing mechanisms in additional studies to safeguard a sound base for further political discussion and possible steps ahead.
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0	0	<p>Biological concepts and conflicting CBD definitions</p> <p>Some biological concepts and terms are not used or referred to properly.</p> <ul style="list-style-type: none"> • Ecosystem “Ecosystem” is a biological concept – i.e. the interrelationship between different organismal groups (e.g. fungi, arthropods, plants and vertebrates) and between organisms and their environment. What the authors actually aim to address is “habitat” – an area with its biota – which can extend beyond different countries (e.g. the Amazon rainforest). Further below, we offer word replacement suggestions to improve the respective scientific accuracy. • Species and genetic Resource The term “species” should not be used as the equivalent of “genetic resource”. This will increase legal insecurity as “species” is a concept which is not regulated neither under the CBD nor the NP. The assignment of a natural entity to a certain species is subject to taxonomic change according to new evidence and the reflections of the taxonomist community. There are a number of examples in which more than one species name is available. If a situation is “transboundary” or not, may depend on different names in the official species list of neighbouring countries solely. In eukaryotes a species is not genetically uniform throughout its range. Merely because a species occurs in more than one place it does not mean that a certain gene or allele of special interest does occur in all places. In this case there is no “transboundary” situation. Furthermore using “species” as a replacement for “genetic resources” could enable countries to claim and authorize access and benefit sharing from utilised “species” occurring in more than one country. This will result in a change in the definition of ‘genetic resource’ and thus overturn the fundamentals of Access and Benefit Sharing, which goes far beyond of the scope of the study. We suggest a careful review of use of these terms as given below. Moreover clarity of concepts and reader friendliness could be improved by providing a separate section with definitions (e. g. insert on page 7, para 9ff)
5	20 and ongoing	The study widely uses the term “country of origin” as a reference for geographical origin or provenance of Genetic resources. To improve the legal clarity on provenance and geographical origin we recommend using the technical term from the CBD respectively the NP “Providing Country”.
4	19-21	Equation of “species” with “genetic resource” (examples for the first subgroup) should be changed according to the general remarks (see above).
4	22-25	Countries already now exercise sovereign rights to grant access to GR occurring on their territory, so it remains unclear what additional legitimate claims can be deduced from Art. 10 NP. Sampling and sequencing blood samples from a migratory species (e. g. cuckoo in Germany) in country A (in full legal compliance) does not require one to contact a second country B (e. g. Cameroon), just because the organism might have (or might have not) spent some time in the second country.
5	3	Replace “shared amongst” with “occur in”
5	8	What exactly is meant by “resources found in the global commons”? DSI? Please specify.
5	11-12 and 16-18	Lines 11-12 in conjunction with lines 16-18 clearly can be understood in a way that the majority of samples in ex situ collections lack key data (passport data). In contrary, data on provenance (collection date, collector, locality, etc.) is available because they are obligatory for the scientific relevance of the samples and their value for basic research. The current wording of this section could be misunderstood. We recommend re-formulating the respective passages.
5	20-21	The lines include the idea that GR from ex situ collections would be frequently used for commercial R&D. This may apply for private collections in the commercial sector (e.g. agro-industry, pharmaceutical, biotech sector), but is rarely the case for GR from Natural History Collections. The authors should make clear, which subgroup they refer to.
6	24ff	The section ‘Methodology’ does not describe how the consulted sources have been analysed and how the results were compiled. Please add more information.

7	9ff	Please insert definition of terms or a glossary to provide more clarity of concepts and reader friendliness. See above.
7	11-15	Please replace 'shared ecosystem' with "habitat".
8	14-15	The title "Specific cases of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations" is misleading as genetic resources do not occur in transboundary situations (see general comments). Please adjust.
8	16-18	As pointed out on page 21, line 14, 50% of the living biomass on Earth is microbial. If the vast majority of microbial life is cosmopolitan (global distribution) and it accounts for half of life on Earth then the extent to which a GMBSM could affect the current implementation of the Nagoya Protocol would be critically important. Consequently, the same may have to apply for all migratory species, seed-dispersed plants, etc. It could be useful to add a few scientific review articles that provide some quantitative, global insight here rather than a single legal review. If helpful the submitting group would be willing to conduct supportive research here.
9	1	Please replace 'Shared Ecosystems' with "Shared habitats or biota" (see general comments).
9	8-9	All examples in this section are from macroorganisms. It could be interesting to consider an example from a microorganism. Human pathogens all share the common habitat of the human body (in addition to environments). Nearly all human pathogens are known to have cosmopolitan distribution. This could be a worthy example to include.
9	2, 5, 7, 12	By definition a species cannot be endemic to more than one country. The authors mean "native". Please adjust in line 2 as well as in line 5, 7, 12
9	10-16	If one applies the concept of <i>in situ</i> and especially <i>ex situ</i> transboundary situations as characterised on page 8 lines 23-27 directly, this will – in our understanding – imply that all domesticated crops and animals worldwide (and their introduction to other countries) would potentially fall under benefit sharing regimes under the NP – is this intended by the authors? If so, we would appreciate a reflection of the authors concerning the possible consequences, since we are convinced, that broad and equal application of the characteristics proposed in this section (see also Scenario 4) will raise even more and fundamental questions like: <ul style="list-style-type: none"> • Economies of most countries in the Global South will be scrutinised (e.g. monetary benefit sharing arising from the cultivation of coffee in Latin America to predominantly IPLCs in the Sudan and Ethiopia or the revenues of tea farming e.g. in East Africa and Asia Minor with East Asian Countries) • Crop and life-stock farming globally will be severely affected (e.g. sharing of benefits arising through the application of TK on domesticated chickens by chicken farmers around the globe with people in Central Asia).
11	Footnote 33	replace "indigenous" with "native" (see above).
13	16	The second citation in footnote 43 seems inappropriate here since the cited submission from the DSMZ is not related to PIC/MAT on ATK. Instead we suggest moving this citation to Section 3.1. We suggest that the DSMZ submission be moved to page 22, line 12-13.
13	20	If the origin of the rosy periwinkle is in Madagascar, it cannot be "endemic" in India (see above) please change "endemic" into "also native in".
14	15	Scientifically speaking, it might be worth considering moving sections 2.1 and 2.3 together. The broader legal challenge is simply that organisms have very different distributions, ecosystem flexibility and habitat range.
16-17		We suggest deleting the Mallard duck (<i>Anas platyrhynchos</i>) example. Only a small fraction of mallard ducks actually migrates and the resident populations are mostly based in those countries that grant free access to GR. If the material that was sourced for patent applications and accessed legally and in compliance with applicable law, why should other countries be "rewarded" (line 5 on page 17)?
18	21	"he" should be "The"
17	7-20 Section 2.4.	BBNJ is being discussed at UNCLOS / UNGA and should be omitted at this study for the time being.

18	1ff	The storage of natural history objects in collections is not a "cross-border situation" but rather an insufficiency in provenance information. In addition, retrospective application would result in increasing administrative effort in the collections and thus be at the expense of research. Publicly funded collections provide urgently needed taxonomic expertise and provide an important historical reference point for understanding global change. Collections thus form the basis for the implementation and monitoring of the CBD, the Aichi Goals, the post-2020 biodiversity targets or the SDGs would be affected. It is important to consider that the combination of either geographical OR temporal scope enables collections to comply with the spirit of the CBD.
19	17ff	The results and considerations presented in section 3.1 (“Genetic Resources of Untraceable Origin in Ex Situ Collections”) mostly refer to publicly available information from publicly funded ex situ collections. These are particularly committed to the objectives of the CBD (namely IPEN, the WFCC and related cultural collections such as the DSMZ and CETAF member institutions). This disregards the cultural, scientific and other non-monetary benefits arising from the mere existence of publicly funded collections and their scientific work and global research networks. Unfortunately private collections held by commercial bodies have not been researched thoroughly in this study although they offer particular potential for a global multilateral benefit-sharing mechanism. We suggest that the authors additionally address how private collections handle these challenges and how a GMBSM could apply here?
19	20-21	There should be a distinction between publicly-funded collections (open to all scientists worldwide) and private ex situ collections with commercial purpose and closed access. Please rephrase.
19	22	Replace “country of origin” with “Providing Country”
20	2-5	Contrary to the authors’ assumption, EU Regulation is of huge relevance for ex situ collections within the EU. It has to be noted that the EU Regulations applies to all users utilising GR within the EU, i.e. also applies to researchers from Africa or South America.
20	5-7	In theory, we agree with the sentence „For countries requiring benefit-sharing for utilization of genetic resources in <i>ex situ</i> collections, a problem arises for specimens deposited without country of origin information, or deposited prior to the CBD or Nagoya Protocol such that PIC, if now required, was not granted“. But we are not aware of an example from the real world. It would be helpful if the authors would state a relevant example.
21	9	It would likely be helpful to the reader to note that this “Africa” sample was collected in 1860. Given that nearly all country borders in Africa have dramatically changed since 1860, any country of origin information is likely irrelevant anyway. Furthermore, it would seem useful to note here or elsewhere in the study that a combination of information – geography and temporal information – can be useful for collections in deciding how to handle material. (See above.)
21	15-16	Microorganisms are generally understood as bacteria, protozoa, algae and fungi. Viruses, plasmids, and cDNA are not considered to be microorganisms because they cannot self-replicate although there is some debate with some viruses.
22	1	Suggest adding several references (https://doi.org/10.1016/j.syapm.2015.02.008 and https://doi.org/10.1093/femsle/fnaa044) and including additional text indicating that culture collections are generally very proactive and aware of CBD- and NP-related obligations.
22	12-13	In addition to moving footnote 43 (as suggested above) we suggest the inclusion of new text after the sentence ending in “a priori”: “Indeed, during the process of becoming a Registered Collection under the EU Regulation 511/2014, the Leibniz Institute DSMZ implemented stringent depositor checks before accepting new deposits. As such, a 20% reduction in deposits was observed. Thus, culture collections that rigorously seek to implement the principles of the Nagoya Protocol are faced with the dilemma whether to continue the scientific collection of novel biodiversity or remain legally compliant.” Additional references: https://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/Register-of-Collections.pdf http://microbiology.publish.csiro.au/?paper=MA19030
22	19-20	Replace “country of origin” with “provider country”.

22	23ff	The primary task of herbaria associated with universities or other research institutes is research, education and conservation. Even if commercial utilization may occur in single cases, there is a remarkable difference to commercial research. Submitting such materials to third parties for commercial research is not in the focus of such ex situ collections. Thus, we are surprised that private ex situ collections are entirely ignored by the authors, since . We suggest rephrasing this section.
24	14	Please delete “species” and adjust this sentence accordingly (see general remarks above).
24	14-15	The statement mostly refers to commercial research. Please change sentence into “However, in commercial research and R&D it is not uncommon...”
25	3	Replace “country of origin” with “provider country”.
25	27-31	The authors refer to the study 4, but not to combined study 2&3. The latter clearly demonstrates that most ‘DSI’ uploaded to INSDC databases originates from the Global North, whilst a number of scientists from the Global South use and utilise this ‘DSI’ for their own research. If “DSI produced from the utilization of a genetic resource could still be subject to benefit-sharing”, this would mean that scientists from the Global South would have to contribute to a GMSBM which will have severe consequences for research activities in the Global South.
26	5	“1600” should be “1,600”
26	9	After “Institute” insert “located in the United Kingdom”.
26	14-19	The authors do not seem to sufficiently acknowledge the massive investments and scientific contribution from non commercial research, which provide the base to recognise, identify and describe biodiversity. Knowledge on biodiversity itself is a precondition for the successful application of any conservation measure. Such knowledge enables states as well as the international community to reach the post-2020 Biodiversity Targets, to support the SDGs, etc.
26	17	Insert “expected to be” in between “data” and “produced”. To our knowledge there has not yet been data produced in this project and no current information on project status is available.
26	21	After “not” insert “have required”. In 2011, the country tag became a required data field. Therefore, the sequences missing country tag information are largely sequences uploaded prior to the coming into force of the Nagoya Protocol.
26	20	Replace “country of origin” with “provider country”.
26	23	Suggest adding the following sentence as mentioned several times in Rohden et al. “The INSDC contents will never reach 100% country information since the origin of sequence data is highly heterogeneous including human data, for example (12% of the dataset) which is not expected or required have a country of origin listed for ethical and patient privacy reasons.”
26	22-23	Scoping study 2&3 revealed that for 56% of INSDC datasets with <u>CBD-relevance</u> , respective passport data is available. The referencing of only 16% of <u>all</u> INSDC by the authors misleading and should be adjusted.
27	17	Delete extra “.”
27	18	Insert “sequence” between “virus” and “strain”
27	20	Should be “Bernard Nocht Institute for Tropical Medicine (BNITM), a member of the Leibniz Association”.

27	14-24	<ul style="list-style-type: none"> To maximize transparency in this often-cited (and non-peer-reviewed literature) case, it would be helpful to note the additional details of this case: The sample in question was collected in March 2014 before the Nagoya Protocol entered into force. Furthermore, Guinea became a Party to the Nagoya Protocol in January 2015. It would have been legally impossible for the BNITM researchers to obtain PIC/MAT from Guinea at the time of the Ebola outbreak. It would also be helpful to cite the original peer-reviewed literature https://www.nejm.org/doi/full/10.1056/NEJMoa1404505 And to note that NEJM has an open data policy that requires authors to submit their sequence data to the INSDC as a pre-requisite for publishing. Furthermore, it could be helpful to note that the authors were undertaking life-risking research for the greater common good and that quick publication in times of outbreaks is of central importance. Costs of non-monetary benefits surrounding the Ebola epidemic. By 22 April 2016, WHO had received over US\$ 459 million in direct and in-kind donations from over 60 donors (mostly from governments and multilateral organisations). Six donors (US, Canada, the UK, Germany, Japan and Norway) alone spent approx. US\$ 190million. By the end of December 2015, the team had deployed over 341 teams on missions to work with Ministries of Health to identify gaps in national capacity, and support the design and implementation of national preparedness plans (Source: https://www.who.int/csr/disease/ebola/funding-requirements/en/) These direct founding very likely excludes (financial) resources allocated e.g. by the German government directly to the Bernhard-Nocht-Institute for Tropical Medicine (BNITM) for basic research on Ebola. The BNITM has long standing relations with the University of Kumasi, Ghana the BNITM operates together with the Ghanaian Ministry of Health the joint facilities in Kumasi together with the University of Kumasi. Besides engagement in Ebola research leading scientist at the BNITM developed the diagnostic tools to identify SARS (as new type of Corona Virus), one of them the new diagnostic kit for COVID-19. The US Government allocated additional US\$ 333 million for R&D to the pharmaceutical company Regeneron. <i>This direct and indirect benefits for Ebola-affected countries (including investments in the development of Ebola-drugs) sum up to over US\$ 792 million For clinical trials 1.108 million US\$ were spent according to https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4389695/ (see table 2)</i> These benefits have to be compared to the direct revenues generated out of the commercialisation of the REGN-EB3 drug. Besides the enormous potential of this new drug, the company did not profit from the in-house investments in the new drug so far, because of “policy-making worries in Washington that could target higher biotech drug prices” and that has “to go through organizations like the WHO and go to Developing Countries”. It does not seem likely that the proposed revenues resulting from the marketing of the REGN-EB3 drug would translate into monetary benefits that could balance what has already been delivered. We suggest rephrasing of this section.
29	Footnote 119	Replace “country of origin” with “provider country”.
29	22	Please replace species with organisms (see general comments above).
30	3-5	The statement is true for traditional breeding lines (either in animals, crops or in microbes) which result in a mixture of “each individual input sequence” from the parent population. Also in classical domestication/propagation “it is virtually impossible to determine the relative value of each individual”. Thus, the example does not provide any further insight and should be removed.
31	2	Delete “and detergents” or add space and additional adjective.
32	4	Delete “,” after “diverse”
34	29	Please delete “shared ecosystems” and rephrase as appropriate (see general comments above).

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